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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,998	07/18/2003	Olaf B. Kinstler	A-822	3557

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EXAMINER

ZEMEL, IRINA SOPJIA

ART UNIT PAPER NUMBER

1711

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,998

Applicant(s)

KINSTLER ET AL.

Examiner

Irina S. Zemel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/18/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 1 and 2 contain specific polymer formulas that are not included or described anywhere in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not provide enabling disclosure of how to make the claimed acetal derivatives (and polyacetal protein conjugates). The specification provides some examples of modification or functionalization of polyacetals, while referring to the underlying polyacetals as polyacetals disclosed in US patent 5,811,510, 5,863,990, and 5,958,398. However, according to the scheme given in column 6 of the referenced patent, the underlying polyacetal (obtained from dextran) contains plurality of hydroxymethyl groups, corresponding to the first segment of polyacetal [acetal]_m of the formula given in claims 2, and CH₂CH₂OH groups as shown in all other fragments of

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formulas claimed in claims 1 and 2. In the illustrative examples of this application, the starting material is dextran, thus, it is not clear how the derivatives claimed in claims 1 and 2 are obtained based on the scheme shown in the referenced patents. Moreover, the specification provides no definitions of *n*, *m* or *a* and *b*. Thus, it does not provide enabling disclosure of the claimed polymers since the exact structure of the polymers is not defined.

Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of making and using the *conjugates* of specifically disclosed acetals derivatives, does not reasonably provide enablement for methods of making of conjugates of any possible acetal derivative known in the art or using any possible acetal-conjugate for the claimed applications. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make specific polyacetalderivative-protein conjugates (provided that the derivatives themselves are enabled by the specification, see discussion above), the invention commensurate in scope with these claims. There is a large number of known acetal derivatives, and specification does not provide enabling disclosure for making protein conjugates of every known acetal derivative. Further, the specification does not provide disclosure commensurate in scope with claimed "acetal-leptin" or "acetal-IL-1ra" conjugate. Moreover, the specification does not provide enablement for "acetal" – conjugate with any protein, since the specification only discloses specific acetal-derivatives, not acetals.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what m and n are referred to since m and n are not defined as either molar, or weight fraction., etc. Furthermore, a and b are not defined at all (claim 2), thus the polymer structure is not understood.

Claim 7 refers to a group of conjugates selected from claim 3 and 4. Claims 3 and 4, while defining some conjugates are NOT conjugates (they are *claims*), and no conjugate can be selected from a claim. Appropriate correction is required.

The specification, while disclosing conjugates of acetal derivatives does not disclose polyacetal-protein conjugates. It is not clear whether "acetal derivative" has the same meaning as "acetal", and thus, the scope of the claims can not be ascertained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by US2002/0082362 to Broccini et al., (hereinafter "Broccini").

The reference discloses a method of conjugating a polyacetal with a protein including all of the claimed steps as described in, for example, [0099-0106]. The invention as claimed, thus, is fully anticipated by the disclosure of the reference.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by US patent 6,048,837 to Friedman et al., (hereinafter "Friedman").

He reference discloses a method of treating obesity by administering to a patient in need thereof a polymer-leptin conjugate. See entire document, for example abstract. Among polymers suitable for conjugation with liptin, polyactals expressly listed in column 23 "Polymer Molecules". The invention as claimed, thud, is fully anticipated by the disclosure of Friedman.

Claims 10 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,294,170 to Boone et al., (hereinafter "Boone")

The reference discloses a method of treating an inflammation by administering to a patient in need thereof a polymer-II-1ra conjugates. See the entire document, especially column 13, line 11, et seq. Among suitable polymers for polymer, polyactals,

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such as those derived from trioxanes are expressly listed in column 13. The invention as claimed, thus, is fully anticipated by the disclosure of Boone..

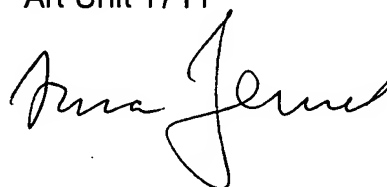
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tomlinson (Bioconjugate Chem) discloses a process of conjugating proteins with polyacetals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina S. Zemel whose telephone number is (571)272-0577. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571)272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irina S. Zemel
Examiner
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